

The Brazilian profile of intellectual property in radiology and imaging diagnosis in an international context in the years 2000 to 2009*

O perfil brasileiro de propriedade intelectual em radiologia e diagnóstico por imagem em um contexto internacional, nos anos 2000–2009

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Abstract Objective: To analyze the Brazilian technological innovation in the field of radiology and imaging diagnosis, in terms of patent indicators. **Materials and Methods:** Exploratory analytical study of information retrieved through cross queries in databases of intellectual property offices in Brazil (State Industrial Property Office [Instituto Nacional da Propriedade Industrial – INPI]), United States (United States Patent and Trademark Office – USPTO) and Europe (European Patent Office – EPO). **Results:** There were 277,057 patents in the field of radiology and imaging diagnosis. Of this total, 7,800 were registered at INPI (3%), 65,428 (24%) registered at the EPO and 203,829 (73%) issued by USPTO. Brazil is a signatory to 1,732 patents published by the INPI, 80 by the EPO and 26 by the USPTO. Overall, 219,993 (79%) patents were related to electronic devices strongly linked to information technology in health care, ultrasonography, tomography, magnetic resonance imaging procedures as well as to images generation, communication and archiving, and 57,064 patents (21%) dealt with technologies related to radiation protection and dosimetry, nuclear physics, electrotherapy, magnetic therapy and radiotherapy. **Conclusion:** The results indicate the weakness of the domestic production of patented technological innovation in the field of radiology and imaging diagnosis. **Keywords:** Medical education; Science and technology; Technological innovation; Intellectual property; Research.

Resumo Objetivo: Analisar a inovação tecnológica brasileira na área de radiologia e diagnóstico por imagem, em termos de indicadores de patentes. **Materiais e Métodos:** Este é um estudo analítico-exploratório de informações recuperadas por meio de consultas cruzadas nas bases de dados dos escritórios de propriedade intelectual do Brasil (Instituto Nacional da Propriedade Industrial – INPI), dos Estados Unidos (United States Patent and Trademark Office – USPTO) e da Europa (European Patent Office – EPO). **Resultados:** Foram encontradas 277.057 patentes. Desse total, 7.800 foram registradas no INPI (3%), 65.428 (24%) registradas no EPO e 203.829 (73%) emitidas no USPTO. O Brasil é o país signatário em 1.732 patentes publicadas no INPI, 80 no EPO e 26 no escritório USPTO. Globalmente, 219.993 (79%) patentes referiam-se a dispositivos eletrônicos ligados a informática em saúde, ultrassonografia, ressonância magnética, tomografia computadorizada e procedimentos de geração, comunicação e arquivamento de imagens, e 57.064 (21%) das patentes tratavam das tecnologias relacionadas a radioproteção e dosimetria, física nuclear, eletroterapia, terapia magnética e radioterapia. **Conclusão:** Os resultados obtidos apontam para a fragilidade da produção nacional de inovação tecnológica registrada em patentes, no campo de radiologia e diagnóstico por Imagem. **Unitermos:** Educação médica; Ciência e tecnologia; Inovação tecnológica; Propriedade intelectual; Pesquisa.

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INTRODUCTION

An aspect of important repercussion for the current scientific-technological debate is the subject of academic research focused on technological innovation, with the possibility of registration and licensing of intellectual property (IP), usually done by means of patents. The discussion on the theme of technological innovation is present in the management of public poli-

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cies by means of economic forums, creation and validation of innovation incentive regulations and research funding programs that result in production of IP and, moreover, as a form of putting the knowledge produced in universities into use to solve actual society's problems.

The speciality of radiology and imaging diagnosis are not distant from such a context, and is certainly one of the most sensitive areas of the medical knowledge as far as technological innovation is concerned⁽¹⁾. This is a consequence of the very configuration of the professional practice in such a speciality, considering that its complex clinical-diagnostic method strongly relies on equipment and modern technological solutions⁽²⁾. In the field of health, the utilization of advanced imaging equipment, computational apparatuses capable of capturing, manipulating and interpreting signs, and even procedures for exchange of electronic data are all originated from technological innovation activities^(3,4).

Every development and creation of IP originates from an innovation process, either formal or informal. The search for innovation occurs at any social segment, from the public sector and its basic services (education and health, for example) to, and principally, the private sector, in companies and industries⁽⁵⁾. The most recognized innovation model is the creation of a new product, totally and sufficiently differentiated from others available in the market. Other forms of innovation also occur in industrial processes of products and services. Such innovation model is focused on modifications in the processes of producing goods⁽⁶⁾. These two forms of innovation are jointly denominated as technological innovation.

The innovation process usually comprises three phases: the conception of an idea, decision making on the adoption of the innovation, and implementation. If the idea is totally new and needs to be developed from an initial concept, such development process is called "creation". However, if the idea already exists and is clearly defined when the innovation process is started, then such a model is called "diffusion"⁽⁷⁾.

Such innovation process is divided into two distinctive innovation categories as

follows: disruptive and incremental. Disruptive innovation occurs as an invention abruptly changes the state of the practice of the current and future technology in the market. On the contrary, incremental innovation only brings specific modifications in the current technological platform of the market.

The technological innovation protection model resulting from the creation of IP is that of international coverage, based on the 1969 Stockholm Convention, which led to the creation of the World Intellectual Property Organization (WIPO)⁽⁸⁾ which establishes, for all signatory countries, the rules for registration, patentability and licensing of intellectual property⁽⁹⁾. Brazil is a member of WIPO and the agency responsible for the registration of intellectual property in the country is Instituto Nacional da Propriedade Industrial (INPI) (National Institute of Industrial Property). In the European Union, the responsible agency is the European Patent Office (EPO)⁽¹⁰⁾, and in the United States of America, the responsible agency is the United States Patent and Trademark Office (USPTO)⁽¹¹⁾.

The present study is aimed at presenting and reviewing the Brazilian IP indicators in the fields of radiology and imaging diagnosis both retrieved, at the domestic level, from INPI patent databases, and, at international level, from EPO and USPTO databases by means of the Espacenet repository, over a period of ten years.

MATERIALS AND METHODS

The method utilized in the present study was based on the analytical-exploratory search model in the fields of "radiology and imaging diagnosis" and "intellectual property and technological innovation". In order to organize the search for data on the production of IP, a search procedure was undertaken over Brazilian (INPI) and international (Espacenet and USPTO) databases. The search over all the databases covered the period from Jan 1st, 2000 to Dec 31, 2009. The search was carried out directly over the Espacenet database. Such a repository provides access to updated European databases, and so do the Brazilian INPI and the North American USPTO databases, besides

those of 90 other countries. Additionally, its search engine allows searches with a complexity level compatible with the method utilized in the present study and with data exportation to the researcher's own databases in a simple manner and at no cost. The search procedure itself consists of the development of a structured method comprising four successive work phases, as described below.

First phase (planning) – Definition of the most representative search terms in the field of radiology and imaging diagnosis. The terms were selected according to the most utilized term "filter" in the list of papers retrieved from the PubMed database (PubMed Clinical Queries) within the theme of radiology and imaging diagnosis, and subsequently such terms were standardized for the present study, according to the index of basic concepts developed by Bushberg et al.⁽¹²⁾, thus favoring the specificity of retrieved data to be analyzed in the present study.

The most representative terms in the field of radiology and imaging diagnosis considered for searches are the following: radiology (*radiologia*), medical imaging science (*imagens médicas*), X-ray (*raios X*), tomography (*tomografia*), ultrasonography (*ultrassonografia*), magnetic resonance imaging (*ressonância magnética*), nuclear physics (*física nuclear*), electrotherapy (*eletroterapia*), magnetic therapy (*terapia magnética*), radiotherapy (*radio-terapia*), picture archiving and communication system – PACS (*sistema de comunicação e arquivamento de imagens*) computer-aided diagnosis – CAD (*diagnóstico assistido por computador*), content-based image retrieval (*recuperação de imagem baseada em conteúdo*), digital imaging communications in medicine – DICOM (*comunicação de imagens digitais em medicina*), health level 7 (HL7)* and health information system – HIS (*sistema de informação em saúde*).

* According to Blazona & Koncar⁽¹³⁾, HL7 is a communication standard which currently represents the basis of several health information management systems. It specifies structures and mechanisms to describe and communicate administrative and clinical data without focusing on a given domain of health or type of communication technology.

Second phase (search) – For extraction and construction of a centralized data repository capable of meeting all objectives and expectations of the present study, three search procedures over the Espacenet were developed. The first procedure defines the office (Brazilian, European or North American) the information will be extracted from. The second procedure refers to the search keywords and their correlation for the international patents classification. Lastly, the third procedure which defines the timeline for the data search.

The first procedure, regarding the data search region, requires that the search field “Select patent database” at the Espacenet platform be defined according to the exact search region. For the search in the European office, the selected field was “EP – complete collection including full text of European published applications”, which represents the database of all European patents. On the other hand, for the search in the Brazilian and North American patent offices, the selected field was “Worldwide – full collection of published patent applications from 80+ countries”, but with a detail: in order to allow that the search is effectively performed in each of the offices, the field “Publication number” must be filled out with the acronym of the country, namely, BR and US for searches over INPI and USPTO databases, respectively.

Once the search standard was defined at each one of the patent offices, the next phase consisted of constructing the search procedure with keywords. Such a procedure was based on the correlation of the keywords in the first phase of the present study method, with the categorization contained on the table of international patents classification^(14,15). With the search of combined keywords and classification categories, it was possible to safely define the parity and the correlation of the search terms in the study with the international coding, thus avoiding, for example, results duplicity or false-negative results in the targeted data retrieval. So, the correlations of keywords and international patents categories were the following: **A61M** representing the terms ultrasonography, MRI, medical image science, X-ray, tomography, radiology; **A61N** representing the terms electrotherapy, magnetic therapy, ra-

diotherapy; **G21F** representing the terms radioprotection, dosimetry; **G21H** representing the term nuclear physics; **G21K** representing the terms X-ray, tomography, radiology, medical image science; and **G06K** representing CBIR, DICOM, HL7, IHS.

Finally, the searches over all the databases were performed covering the period from Jan 1st, 2000 to Dec 31, 2009. For this purpose, the field “Publication date” was filled out with the values 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008 and 2009. All the results from each search were exported in a comma-separated format (*.csv) and imported into a database specifically created for the present study.

Third phase (compilation) – The files exported from the Espacenet database, containing the relevant data for the search, were imported into a MySQL⁽¹⁶⁾ database specifically created for the present study. The fields included on the database were: ID, Office, Title, Publication number, Publication date, Applicant(s), Inventor(s), European Classification (ECLA), International Patent Classification (IPC), application number and abstract.

Fourth phase (search) – The composite terms were searched at the third phase, by utilizing the Boolean⁽¹⁷⁾ search language for composite terms and also for their respective acronyms, which in the totality of the cases are the same in Portuguese and English. The searches based on terms occurred in the options “title” and “title and abstract” of the queried databases. A list of SQL query commands was elaborated with the objective of avoiding the data retrieval with high sensitivity and low specificity during the third and fourth phases.

The comparative analysis of the obtained results was based on a literature review in the same areas focused by the present study. The patents filed regarding development of pharmaceuticals for use in the field of radiology and imaging diagnosis were not considered in the present study. The searches on the international Espacenet database were performed considering the global production of filed patents (search option Worldwide) with the objective of obtaining the thematic coverage (scope) of the present study.

RESULTS

The data retrieved from the domestic and international databases, considering all the keywords indistinctively for all the databases, comprised 277,057 patents filed at the three patent offices (EPO, INPI, USPTO), in the scenario researched by the present study (100%). From those, 4,544 patents were filed at INPI (2.4%). The query in SQL on database retrieved and developed in the search scope has allowed the configuration and grouping of the 277,057 patents into categories representative of the international classification (nomenclature) of patents (Table 1), so it was possible to establish that the regional office with the highest number of filed patents in the area of interest is the USPTO (Table 2). However, the European Office is the international office most utilized by Brazilian patent authors for the filing of such patents, with 80 patents (Table 3).

DISCUSSION

As a whole, the results obtained by the search procedure allowed the current overview on the Brazilian production of technology in the field of radiology and imaging diagnosis as well as in its correlates, developed by their several agents along the 2000–2009 decade. Such data confirm a significant variation between domestic and international productions (Tables 2 and 3). The number of foreign patent applications filed at INPI is much higher than the number of domestic patents filed at the same office. As expected, the regional office holding the highest number of patent applications is the USPTO, either for representing the largest economy in the global scenario, or for the fact that the USA promotes the creation of new products and services by means of important programs for financing research and development targeted to small and medium sized companies⁽¹²⁾ and even for adopting a more permissive regulation in terms of what is eligible for filing as IP (for example, a software IP can be protected by means of patent in the USA, but not in Brazil).

A comprehensive view on the data in the categories and keywords utilized in the construction of the search procedure dem-

Table 1 Organization of the results found in groups, utilizing the classes and categories of the international classification of intellectual property⁽¹⁵⁾.

Definition	International classification	Equivalence (scope) in/such terms
Group A	Human needs	
A61M	Devices to insert materials into the body or to deposit them over the body	Ultrasonography, MRI, medical image science, X-ray, tomography, radiology
A61N	Electrotherapy; magnetotherapy; radiation therapy; ultrasound therapy	Electrotherapy, magnetic therapy, radiotherapy
Group G	Physics	
G06K	Data identification; data presentation; data transportation; manipulation of data transportation	CBIR, DICOM, HL7, IHS, PACS, CAD
G21F	Protection against X-radiation, gamma radiation, corpuscular radiation or particle bombardment; treatment of radioactively contaminated material; decontamination arrangement	Radioprotection, dosimetry
G21H	Obtainment of energy from radioactive sources; application of radiation from the radioactive sources; utilization of cosmic rays	Nuclear physics
G21K	Techniques for manipulation of particles or electromagnetic radiation not included in other location; irradiation devices; gamma or X-ray microscopes	X-ray, tomography, radiology, medical image science

Table 2 Records retrieved by the study, at each researched (domestic and international) database, comprising all patents filed in the classifications covered by the study.

	G21F	G21H	G21K	A61M	A61N	G06K
EPO	2,203	117	2,740	32,507	12,415	15,446
USPTO	5,370	993	10,383	80,514	34,530	72,039
INPI	346	23	94	4,822	1,067	1,448

EPO, European Patent Office; USPTO, United States Patent and Trademark Office; INPI, Instituto Nacional da Propriedade Industrial.

Table 3 Records retrieved by the study, at each researched (domestic and international) database, comprising all filed patents, exclusively by Brazilians, in the classes covered by the study.

	G21F	G21H	G21K	A61M	A61N	G06K
EPO	2	0	6	34	13	25
USPTO	0	0	1	16	2	7
INPI	24	0	15	1,075	313	305

EPO, European Patent Office; USPTO, United States Patent and Trademark Office; INPI, Instituto Nacional da Propriedade Industrial.

onstrates a concentration of innovation in radiological apparatuses and related techniques in the “A” definition group (Table 1) and a large number of IP filings in the area of information technology in health and medical physics applied to radiology and imaging diagnosis in the definition group “G” (Table 1). On the author’s opinion, the G06K category (Table 1), is a *sui generis* classification for comprising characteristics of both groups, as the innovation products filed in that category are related to the procedures of generation, archiving and transmission of radiologic images, with repercussions both on equipment and hardware/software platform for operation

of health apparatuses. By first considering the patent filings by Brazilians at the USPTO with respect to the “G” definition group (Table 1), and the classification G21F and G21H, no patent filing was found (Table 3). The G21F classification (Table 1) only received publication of patents by Brazilians in the European office (2) and in the Brazilian Office (24) (Table 3). Such a classification, by its own description, points towards products and devices in the area of radioprotection. Over the last decade, radiation protection and dosimetric control have received increasing attention in what regards medical applications and clinical investigation under-

taken in universities⁽¹⁸⁾. In this scenario, one highlights the development of new technologies and applications that rely on high intensity and high accuracy radiation fields with short duration and high repetition rates at shorter time intervals. Such new technologies comprise aspects targeted at imaging diagnosis, particularly in the field of nuclear medicine and treatment, with focus on radiotherapy, involving from X-ray accelerators to neutron sources⁽¹⁹⁾. Such new technologies have the potential of minimizing the deleterious effects and risks for patients exposed to ionizing radiation, allowing the disposal of nuclear materials in a more appropriate and controlled manners by the institutions, and possibly lowering the costs associated with safety apparatuses required in health care processes. Therefore, it is a constitutive element of the radiology clinical practice, with a considerable impact on the professional daily activities. The category G21H (Table 1) concerns the obtainment and application of nuclear energy for radiology and general health devices. Such a classification is the only among all categories in the present study for which no Brazilian patent filing was detected at any of the patent offices (Table 3). Such a situation is added to the fact that all the 23 patents found at INPI (Table 2) belong to foreign applicants with some kind of commercial/licensing and product protection interest in the Brazilian territory. Additionally, such category is also

the smallest in number of publications, among all others in the studied spectrum (Table 2). The reason for such a small number of IP publications, even in a global context, remains unknown to the present study authors. By utilizing only the study method, it is not possible to qualitatively determine whether the filed patents indicate a frontier of innovation in radiology and imaging diagnosis or an area that is already well developed (comparison, for example, with the previous decade and/or complete reading of each patent. Some studies fragments^(4,6,13) indicate that it is a problem related to the type of research (radioactive energy) and political/legal prohibitions (even in the USA), besides the high cost and poor results in the state of current practice. It is also possible to speculate on the number of researchers involved with projects on this theme. The G21H class (Table 1) is a nomenclature applied to devices that utilize direct manipulation of radioactive residues in nuclear reactors utilized in health care. Among all the strands of innovation covered by the present study, such particular category, on account of its characteristics respecting the manipulation and use of strictly controlled materials, is the one with smaller number of publications in all international offices, even considering the authors from other foreign communities.

On the other hand, the G21K category (Table 1), received publications from all international offices approached by the present study. Among all the investigated categories, G21K was the one with the most even distribution of domestic and international patents, 7 and 15 patents respectively (Table 3). Such category comprises products related to the utilization of electromagnetic radiation (with emphasis on ionizing radiation) in medical imaging apparatuses, such as X-ray and computed tomography equipment, and is particularly related to devices aimed at optimizing the images acquisition process.

Such a small number of patents under the classification scope related to the definition group "G" (Table 1), with the exception of category G06K, which will be analyzed together with group "A" (Table 1) for their thematic proximity, suggests three different possible scenarios. The first one

is that the academic community and the Brazilian technological base do not produce sufficiently relevant products eligible for patent applications in large international markets. The second possible scenario is that in which Brazil develops domestic solutions, particularly those available at public hospitals and with the utilization of open source technologies and/or use of open knowledge (scientific articles and papers, etc.). The third scenario is that in which Brazil is a large importer of technology and products related to the types of patents with small number of publications. Also, there is the strong possibility that these three scenarios are actually co-existing, thus determining the small number of patents in the area. This may demonstrate an inexpressive dynamics between theoretical knowledge produced by the Brazilian universities and the application of such knowledge in the resolution of actual problems in the practice of, in such case, a clinical speciality.

The definition group "A" (Table 1), on its turn, presents the highest number of patent filings found in the present study. Category A61M, specifically, respecting the clinical practice of radiology and imaging diagnosis by means of technological devices related to ultrasonography, magnetic resonance imaging, radiography and medical radiology. It was the category with the highest number of patent filings in all the investigated scenarios (Table 2), also comprising the highest number of invention applications filed by Brazilians in Brazil and, in its totality, also abroad. Category A61N (Table 1), on its turn, comprises the highest number of instruments related to radiotherapy, electrotherapy and magnetic therapy. Finally, category G06K (Table 1) comprises identification, manipulation, transmission and archiving of recorded data. With the technological advances in the acquisition and utilization of medical images, radiology has presented intellectual and financial developments^(20,21). The improvements in the offer of information technology, particularly in procedures connected with transmission of medical data, such as HL7 and DICOM itself, allow an easier and dynamic development of the diagnosis by the radiologist and by the area that requested the examinations. Together,

such characteristics encourage investments in academic and entrepreneurial research with strong possibilities of generating innovation and IP, even when competing for space, and as a matter of fact, increasingly so, with freeware and user friendly solutions available for radiologists^(22,23).

The number of patents filed in a country demonstrates the relevance and the level of development which such target-country represents for the object of the patent⁽²⁴⁾. Thus, it is assumed that as Brazil is chosen as a protected place for one's invention, the author does not only wish to market his invention locally, but also to protect his product from any potential competitor in that country. Thus, considering the fact that most patents filed at the international offices are not filed at INPI (Table 2) one may conclude that there is neither commercial interest nor interest in the development of protection of such intellectual property in Brazil, for most patents found in the present study (Table 3). This is equivalent to mention that the country is not only economically not viable for the licensing of technology or industrialization of medical radiological equipment based on technological innovation, mainly those related to nuclear materials in the "G" definition group (Table 1), but also that the country's research & development platform is still producing innovation at a very slow pace in all investigated categories. Considering the theme investigated in the present study, this is rather worrisome, as more people will have access or will demand access to more expensive and complex imaging studies⁽²⁵⁾. Additionally, modern evidence-based medicine increasingly demands examinations with more reliable results, with lower risk both to patients and the specialist and at accessible operational cost⁽²⁶⁾, which can only be attained with a research & development platform strongly focused on science, technology and innovation⁽²⁷⁾.

CONCLUSION

The data presented in this study allow varied approaches for the discussion on the kind of production, sub-areas of research & development and dissemination of technological innovation on the approached theme; however, it is important to highlight

the weakness of the Brazilian IP production in the fields of radiology and imaging diagnosis, in what respects the filing of such IP at domestic and international offices. As a future prospect to widen the discussion on the Brazilian situation with respect the theme presented in this study, there is the possibility of a new study with a exploratory-comparative bias on the situation of Brazil with those of other emerging countries (China, India and Russia) and even of other regions not covered by the method in the present study (Asia and Oceania).

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